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Dkt. 51917-CB-PCT-US/JPW/AJM/AAB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: David J. Pinsky et al.  
Serial No.: 10/692,439  
Filed : October 22, 2003  
For : METHODS FOR TREATING ISCHEMIC DISORDER AND  
IMPROVING STROKE OUTCOME

1185 Avenue of the Americas  
New York, New York 10036  
June 15, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56 and 37 C.F.R. §1.97, applicants would like to direct the Examiner's attention to the following publications which are listed on the attached Form PTO-1449 (**Exhibit A**). Copies of cited publications 16, 28 and 41 are attached hereto as **Exhibits 1-3** respectively. Publications 26, 45, 48-53, 55, 60-62, 64, 67, 69, 70, 72, 73, 80, 81 and 84 are of record in prior application U.S. Serial No. 08/721,447, filed September 27, 1996, to which priority under 35 U.S.C. §120 is claimed. Publications 1 and 47 are of record in prior application U.S. Serial No. 09/053,871 filed April 1, 1998, to which priority under 35 U.S.C. §120 is claimed. Publications 2-15, 17-25, 27, 29-40, 42-44, 46, 54, 56-59, 63, 65, 66, 68, 71, 74-79, 82, 83, 85 and 86 are of record in prior application U.S. Serial No. 09/671,100, filed

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September 27, 2000, to which priority under 35 U.S.C. §120 is claimed. According to 37 C.F.R. §1.98(d), copies of patents or publications that are of record in such prior applications need not accompany this Information Disclosure Statement.

1. U.S. Patent No. 4,711,848, Insley et al., Site Specific Mutagenesis in Alpha-1-Antitrypsin, issued December 8, 1987.
2. U.S. Patent No. 4,885,277, Nawroth, Anticoagulant therapy, issued December 5, 1989.
3. U.S. Patent No. 5,169,786, Carroll et al., Method of determining levels of extrinsic and intrinsic clotting factors and protein C, issued December 8, 1992.
4. U.S. Patent No. 5,378,464, McEver, Modulation of inflammatory responses by administration of GMP-140 or antibody to GMP-140, issued January 3, 1995.
5. U.S. Patent No. 5,443,960, Dahlback, Method for the diagnosis of blood coagulation disorders, issued August 22, 1995.
6. U.S. Patent No. 5,472,850, Morrissey, Quantitative clotting assay for activated factor VII, issued December 5, 1995.
7. U.S. Patent No. 5,498,601, Sato et al., Platelet aggregation-inhibiting peptides, issued March 12, 1996.

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8. U.S. Patent No. 5,602,233, King, Process for production of inhibited forms of activated blood factors, issued February 11, 1995.
9. U.S. Patent No. 5,618,788, Capon et al., Preparation of functional human factor VIII and pharmaceutical treatment therewith, issued April 8, 1997.
10. U.S. Patent No. 5,807,980, Lasters et al., Bovine pancreatic trypsin inhibitor derived inhibitors of factor VIIa-tissue factor complex, issued September 15, 1998.
11. U.S. Patent No. 5,839,443, Rose et al., Method for Inhibiting Thrombosis in a Patient Whose Blood is Subjected to Extracorporeal Circulation, issued November 24, 1998.
12. U.S. Patent No. 5,962,266, White et al., Protease inhibitor peptides, issued October 5, 1999.
13. U.S. Patent No. 6,315,995 B1, Pinsky et al., Method for Treating an Ischemic Disorder and Improving Stroke Outcome, issued November 13, 2001.
14. U.S. Patent No. 6,316,403 B1, Pinsky et al., Method for Treating an Ischemic Disorder and Improving Stroke Outcome, issued November 13, 2001.
15. U.S. Patent No. 6,391,300, Rose et al., Method for Inhibiting Thrombosis in a Patient Whose Blood is Subjected to Extracorporeal Circulation, issued May 21,

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16. WO 94/05314A, Peptide Inhibitors of Leukocyte Adhesion, Centocor Inc., March 17, 1994 (**Exhibit 1**).
17. PCT International Application No. WO 94/22885, Kisilvesky et al., Queens University, Anticoagulant Compounds, published October 13, 1994.
18. WO 95/17421, Peptide Analogs of the Factor Ixa Platelet Binding Site, Walsh et al., Temple University, June 29, 1995.
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20. WO 96/00577, Agents Affecting Thrombosis Hemostasis, Sinha et al., COR THERAPEUTICS INC (US), January 11, 1996.
21. WO 97/42900, Trustees of Columbia University, Rose et al., Method for Inhibiting Thrombosis in a Patient Whose Blood is Subjected to Extracorporeal Circulation, published November 20, 1997; filed May 15, 1997.
22. WO 98/13058, Trustees of Columbia University, Pinsky et al., Method for Treating an Ischemic Disorder and Improving Stroke Outcome, published April 2, 1998; filed September 25, 1997.

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24. WO 99/49880, Trustees of Columbia University, Pinsky et al., Method for Treating an Ischemic Disorder and Improving Stroke Outcome, published October 7, 1999; filed April 1, 1999.
25. Australian Patent No. 735258, Trustees of Columbia University, Rose et al., Method for Inhibiting Thrombosis in a Patient Whose Blood is Subjected to Extracorporeal Circulation, issued July 5, 2001.
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27. U.S. Serial No. 09/053,872, Rose et al., Method for Inhibiting Thrombosis in a Patient Whose Blood is Subjected to Extracorporeal Circulation, filed April 1, 1998.
28. U.S. Serial No. 10/679,135, Pinsky et al., Methods for Teating Ischemic Disorders Using Carbon Monoxide, filed October 3, 2003.
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30. International Preliminary Examination, April 20, 1998  
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32. International Search Report, June 18, 1999 for  
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33. International Preliminary Examination, January 7, 2000  
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34. Search Report, May 28, 2002 from Patent Office  
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52. Connolly et al. (1996) Procedural and Strain-Related Variables Significantly Affect Outcome in a Murine Model of Focal Cerebral Ischemia. Neurosurgery. 38:523-532.
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Pursuant to 37 C.F.R. §1.97(b)(3) no fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Alan J. Morrison  
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6/15/07  
Date

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<b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)					Applicants: David J. Pinsky et al.								
					Filing Date October 22, 2003		Group						
<b>U.S. PATENT DOCUMENTS</b>													
Examiner Initial		Document Number			Date	Name	Class	Subclass	Filing Date if Appropriate				
		4	7	1	1	8	4	8	12/8/1987	Insley et al.	435	69.2	
		4	8	8	5	2	7	7	12/5/1989	Nawroth	514	15	
		5	1	6	9	7	8	6	12/8/1992	Carroll et al.	436	69	
		5	3	7	8	4	6	4	1/3/1995	McEver	424	143.1	
		5	4	4	3	9	6	0	8/22/1995	Dahlback	435	13	
		5	4	7	2	8	5	0	12/5/1995	Morrissey	435	13	
		5	4	9	8	6	0	1	03/12/1996	Sato et al.	514	17	
		5	6	0	2	2	3	3	2/11/1995	King	530	381	
		5	6	1	8	7	8	8	4/8/1997	Capon et al.	514	12	
		5	8	0	7	9	8	0	4/8/1997	Lasters et al.			
		5	8	3	9	4	4	3	11/24/1998	Rose et al.	128	898	
		5	9	6	2	2	6	6	10/5/1999	White et al.	435	692	
		6	3	1	5	9	9	5	11/13/2001	Pinsky et al.	424	94.63	
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		6	3	9	1	3	0	0	5/21/2002	Rose et al.	424	145.1	
<b>FOREIGN PATENT DOCUMENTS</b>													
		Document Number			Date	Country	Class	Subclass	Translation				
									Yes	No			
		9	4	0	5	3	1	4A	3/17/1994	WO (Exhibit 1)			
		9	4	2	2	8	8	5	10/13/1994	WO			
		9	5	1	7	4	2	1	6/29/1995	WO			
		9	5	3	4	3	1	9	12/21/1995	WO			
		9	6	0	0	5	7	7	1/11/1996	WO			
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		9	8	1	3	0	5	8	4/2/1998	WO			
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		9	9	4	9	8	8	0	10/7/1999	WO			
			7	3	5	2	5	8	11/20/1997	AU			
		2	1	4	1	6	4	2	3/8/1995	CA			
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>													
		U.S. Serial No. 09/053,872, Rose et al., Method for Inhibiting Thrombosis in a Patient Whose Blood is Subjected to Extracorporeal Circulation, filed April 1, 1998.											
		U.S. Serial No. 10/679,135, Pinsky et al., Methods for Treating Ischemic Disorders Using Carbon Monoxide, filed October 3, 2003 (Exhibit 2)											
EXAMINER					DATE CONSIDERED								
* EXAMINER: Initial if citation considered. whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.													

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		International Preliminary Examination, April 20, 1998 for PCT/US97/08282.			
		Search Report October 27, 2000 from Patent Office regarding European Patent Application No. 97926541.0.			
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		Partial European Search Report, March 1, 2004 from European Patent Office on European Patent Application No. EP 97944453.6 (Exhibit 3).			
		Bajaj et al. (1992) Antibody-probed conformational transitions in the protease domain of human factor IX upon calcium binding and zymogen activation: putative high-affinity Ca(2+)-binding site in the protease domain. Proc. Natl. Acad. Sci. USA 89:152-156.			
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		Benedict C.R. et al. (1991) Active Site-Blocked Factor IXa Prevents Intravascular Thrombus Formation in the Coronary Vasculature Without Inhibiting Extravascular Coagulation in a Canine Thrombosis Model. J. Clin. Invest. 88:1760-1765.			
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		Bronner et al. (1995) Primary prevention of stroke. The New England J. Med. 333:1392-1400.			
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		Dietrich et al. (1995) Influence of High-Dose Aprotinin on Anticoagulation, Heparin Requirement, and Celite-and Kaolin-Activated Clotting Tie in Heparin-pretreated Patients Undergoing Open-Heart Surgery. Anesthesiology, 83(4) 679-689.			
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		Furie, B.C. and Furie, B. (1995) Biosynthesis of Factor IX: Implications for Gene Therapy. Thrombosis and Haemostasis 74:274-277.			
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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				Applicants: David J. Pinsky et al.	
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